INFUSION DEVICE ANALYZER
MODEL IDA-2

OPERATOR'S MANUAL

BIO-TEK
INSTRUMENTS, INC.

Highland Park, BOX 998
Winooski, Vermont 05404-0998 USA
Phone: 802-655-4040

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BIO-TEK® INSTRUMENTS, INC

INFUSION DEVICE ANALYZER

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REVISION A

BIO-TEK INSTRUMENTS, INC.
HIGHLANDPARK, BOX 998
WINOOSKI, VERMONT 05404-0998 USA
802-655-4040
800-451-5172
800-24-BIOTK (SERVICE)
TELEX: 94-0136 BIO TEK SHVT
FAX: 802-655-7941

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INTRODUCTION TO THE MODEL IDA-2 OPERATOR'S MANUAL

This document is the operator's manual for the Bio-Tek Infusion Device Analyzer Model IDA-2, a description of it's contents, and instructions for it's use. It does not contain instructions or documentation required to service the unit. **If a problem develops, the user should contact Bio-Tek at: 1-800-451-5172.** The user should never attempt to service the unit before consulting Bio-Tek personnel.

The objectives of this manual are to provide:

1. General information about the Model IDA-2, including applications (Section 1);

2. Warnings, shipping, and storage instructions (Section 2);

3. Description of the unit and specifications (Section 3);

4. Detailed operating instructions and descriptions of specific tests (Section 4);

5. Maintenance, service, and calibration procedures (Section 5);

6. Theory of operation (Section 6); and

7. Troubleshooting (Section 7);

1 GENERAL INFORMATION

1.1 Overview

The Bio-Tek Infusion Device Analyzer Model IDA-2 provides a simple method of checking the performance of most continuous flow medical infusion pumps and controllers. These devices can be volumetric, peristaltic, or drop-counting types or motorized syringes. The Model IDA-2 measures flow rates in the range of 0.5 ml/hr to 1000 ml/hr and measures occlusion (stall) pressures up to 240 kPa (36 psi or 2.4 Bar). The Model IDA-2 is a quality assurance instrument that enables service engineers to verify device performance.

1.2 Applications

- The Model IDA-2 can be used on the bench in a service department or on the patient floor. The instrument clamps onto a drip pole or a similar stand.

- The Model IDA-2 can be used to quickly verify the performance of infusion pumps and controllers. Readings for Instantaneous and Average Flow Rates, Cumulative Volume Delivered, and Occlusion Pressure can be obtained in a very short time.

- Steady flow pumps (e.g., syringe pumps) that operate at low flow rates can be tested for flow rate in the time taken to deliver approximately 0.1 ml.

- Non-steady flow pumps or controllers (e.g., drop-counter, peristaltic, or volumetric pumps) can be tested; the test results will depend on when the test was performed during the pump cycle. For these types of equipment the **AVERAGE FLOW RATE** is the most important test result.

- The fluid outlet connector of the Model IDA-2 can be pressurized in the range of +300 mmHg to -100 mmHg by using an additional suitable apparatus to test flow rate under various back-pressure conditions. (See section 4.13 for further information).

- Occlusion (stall) pressure tests can be performed to show the increase in pressure when the infusion device tubing is occluded. At the culmination of this test, the maximum pressure achieved by the pump before it stalls or sounds the overpressure alarm is displayed. If the pressure exceeds 240 kPa (36 psi, 2.4 Bar), then the Model IDA-2 is automatically reset to the quiescent mode. A printout of the test results can be obtained for documentation

- A printer can be connected via a standard Centronics parallel interface. The printout of all tests can be included in the service records and can provide verification of equipment testing when required for legal records. The printer can print every measurement made or it can print at intervals of approximately every 5 or 60 minutes, as selected by the operator. All printed results include the current date and time of test; there is also space for additional information relevant to the infusion device being tested.

- The test data from the Model IDA-2 can also be transferred to an external computer for further data manipulation via the serial port.

  A computer program is available for the Model IDA-2 for graphics presentation of flow and occlusion test results. The program (Version 2.0 and later) also allows some control of the IDA-2 from the computer keyboard. Operation of the program is described in the **Operator's Manual for the Graphics Capture Program,** normally supplied (bound) with this manual.

2 WARNINGS, SHIPPING AND STORAGE INSTRUCTIONS

2.1 WARNINGS

2.1.1 Patient Circuit

The Model IDA-2 has been designed for testing infusion devices but must NEVER be used while connected to a patient. The inside can be disinfected, but not fully sterilized.

2.1.2 Contamination of Measuring System

1. **Best results are using degassed water. However, bubble free tap-water is normally satisfactory.** One can also use other low-viscosity fluids such as saline; however, we recommend flushing the internal system of the Model IDA-2 with clean water after using these other fluids. High viscosity fluids cannot be used. Liquid containing oils may also damage the mechanism.

2. To extend the life of the transducer and to maintain accuracy it is recommended that periodically a few ml of mild detergent solution be introduced into the fluid inlet port, left for 5 minutes, and then flushed out with 500 ml of clean water.

3. Care should be taken to prevent dirt, dust, metal swarf, or other debris from entering the measuring system since these are likely to damage the mechanism.

2.1.3 Explosion Risk

The Model IDA-2 is not to be used in the presence of flammable anesthetic gases or vapors.

2.1.4 Switching the Model IDA-2 ON or OFF

As is common with most other computing equipment, the Model IDA-2 may be damaged by repeated interruption of the power supply, either by rapid switching ON or OFF, or by removing the line cord when the instrument is energized. After switching OFF allow at least 3 seconds before switching the unit ON. Never disconnect the line cord without first switching the unit OFF.

The ON/OFF switch of the Model IDA-2 is located on the rear panel of the unit.

2.2 Storage and Shipping

2.2.1 Removing Internal Water before Shipping or Storage

Before long-term storage or shipping it is recommended that all internal water be removed from the Model IDA-2. After manufacture and testing, internal water is removed by connecting the FLUID OUT port on the Model IDA-2 to a (medical) suction pump for 5 minutes in the 'Lamp Test' mode (see section 7.2, Lamp Test). Users may wish to employ this method, which will not harm the Model IDA-2.

Do not use compressed air to clear out internal water since pressures greater than 240 kPa (36 psi) may damage the pressure transducer.

2.2.2 Storage and Packing

1. Remove as much internal water as possible (as described in section 2.2.1 above).
2. Store away from sunlight.
3. Protect from frost (internal water may freeze and expand)
4. Protect from vibration and shock

3 DESCRIPTION AND SPECIFICATIONS

3.1 Model IDA-2 Description

3.1.1 Front Panel Description

The following components on the Model IDA-2 front panel are shown in Figure 3.1.

LED Display	The light emitting diodes display up to 4 digits for the units of measure chosen
ml/hr; kPa; Psi	Indicators for the units of measure *milliliters per hour*, *kiloPascals*, and *Pounds per square inch*, respectively. These are located to the right of the LED display.
RESET (R)	The reset button is used to reset the IDA-2 to quiescent mode. Pressing this button a second time causes a header to be printed.
INST/AVG FLOW (F)	The normal Flow Test Mode is activated by depressing this touch pad; the initial default is the Instantaneous Flow Test. When the touch pad is depressed again the unit displays the overall average flow rate.
HI ACC'Y FLOW TEST/VOLUME	A higher accuracy flow test is initiated by depressing this touch pad. Once the test is initiated the calculated delivered volume can be displayed by pressing this touch pad.
OCCLUSION TEST/PRESSURE	The Occlusion Pressure Measurement Mode is activated by pressing this touch panel.
IMMEDIATE (I)	When this touch pad is pressed the operator instructs the printer to print out successive current (instantaneous) values.
5 MINS (M)	When this touch pad is pressed, the operator instructs the printer to print out results only at intervals of 5 Mins (approx.).
1 HOUR (H)	When this touch pad is depressed the operator instructs the printer to print out results only at intervals of 1 hour (approx.).

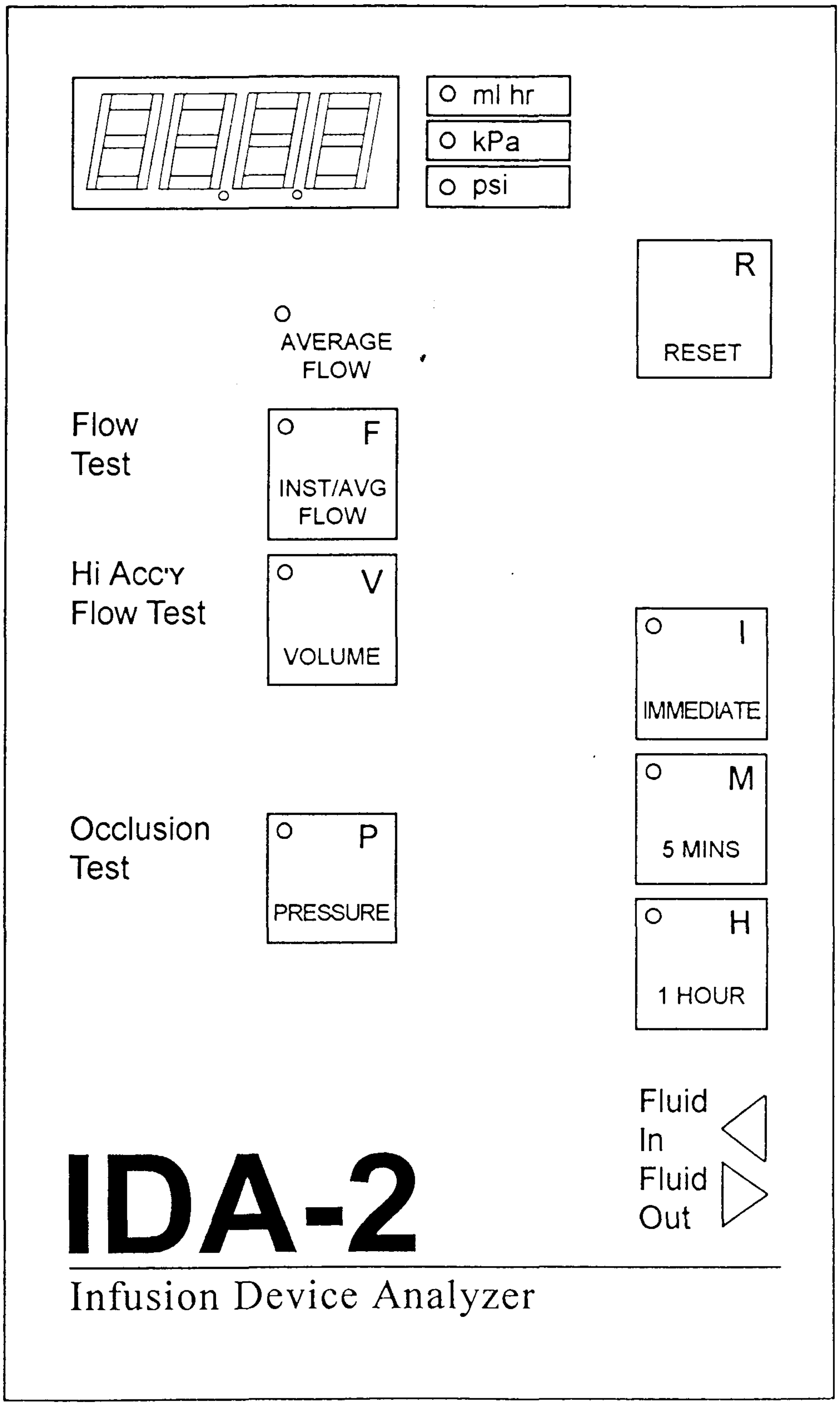

Figure 3.1 - IDA-2 Front Panel

Fluid In ◂ The fluid inlet of the Model IDA-2 is designated on the front panel; the inlet is located in the right side panel of the instrument.

Fluid Out ▸ The fluid outlet of the Model IDA-2 is designated on the front panel; the outlet is located on the right side panel of the instrument

3.1.2 Rear Panel Description

The ON/OFF switch for the Model IDA-2 is located in the rear panel of the instrument. The *parallel*, or printer port and *serial RS232*, or computer port are located on the rear panel of the Model IDA-2. See Figure 3.2 for the layout of the rear panel.

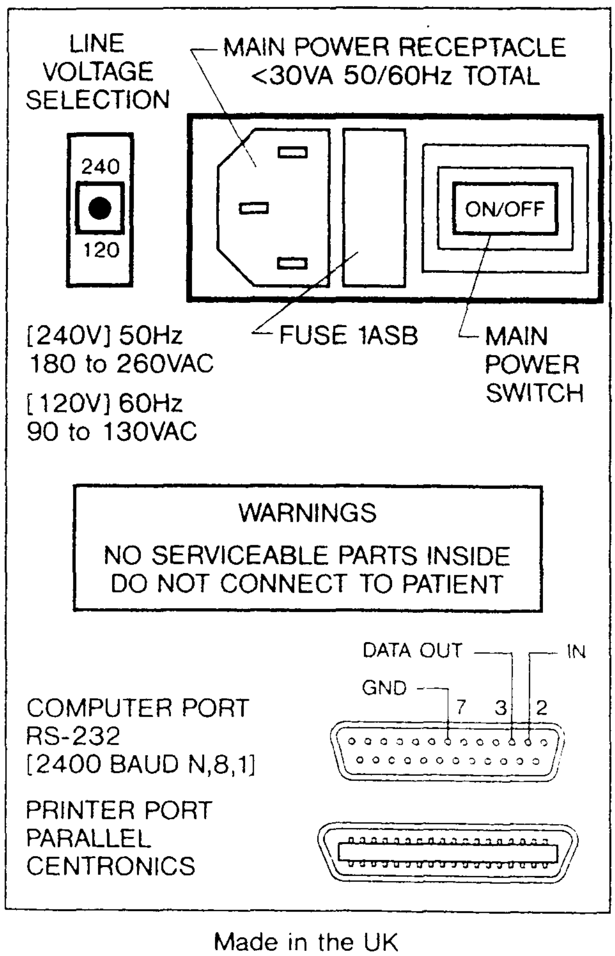

Figure 3.2 - IDA-2 Rear Panel

3.1.3 Short-Form Instructions Overlay

The Model IDA-2 has a short-form instructions overlay positioned on the top of the unit. This overlay provides the operator with *brief* operating instructions. The overlay is shown in Figure 3.3.

IDA-2 SHORT FORM INSTRUCTIONS

1. Connect infusion device to **FLUID IN**, drain tube to **FLUID OUT**.
2. Switch on IDA-2. Display will show '**---P---**'.
3. Prime IDA-2 by perfusing WATER from the infusion device. IDA-2 displays '**------**', when ready to test.
4. Set infusion device to desired rate and delivery volume.
5. **High Accuracy** measurements: Press test key '**V**' before any other test key; an '**H**' will appear in the display.
6. **Instant Flow Rate**: Press test key '**F**'.
7. **Average Flow Rate**: Press '**F**' again.
8. **Cumulative Volume**: Press '**V**'.
9. **Occlusion Pressure**: Press Reset '**R**', then Pressure '**P**'. Press '**P**' again, for kPa or psi.
10. Press '**R**', repeat step 3, to do another test after Occlusion test.

Figure 3.3 - Short-Form Instructions Overlay

3.2 Specifications

NOTE: These specifications are for the guidance of users and do not represent a contractual statement of performance under all possible circumstances.

Digital presentation of all measurements means that all stated accuracies are subject to a ±1 Least Significant Digit (LSD) qualification.

3.2.1 Electrical Specifications.

Supply Voltage	70 - 130 VAC or 200 - 260 VAC (switch selectable)
Supply Frequency	50 - 60 Hz
Supply Power	< 30 VA
Fuse	20 mm 250 V, 1 A(T) (slow blow)
Earth Leakage Current	< 0.5 mA in single-fault condition

3.2.2 Current or *Instantaneous* Flow Rate Accuracy

Accuracies are for % of reading for steady flow devices.

Normal Flow Mode (not hi-acc'y)

Infusion Device Setting	Accuracy	Typical time to first reading
<1 ml/hr	±4%	> 6 mins
1 ml/hr	±4%	6 mins
10 ml/hr	±4%	50 seconds
100 ml/hr	±2%	25 seconds
500 ml/hr	±2%	25 seconds
1000 ml/hr	±4%	25 seconds

Hi-Accuracy Flow Mode

<1 ml/hr	±2	
1 ml/hr	±2	1 hour
10 ml/hr	±2	6 mins
100 ml/hr	±2	50 seconds
500 ml/hr	±2	25 seconds
1000 ml/hr	±4	25 seconds

NOTES:

1. The range of the current (*instantaneous*) flow measurement is from 0.5 - 1000 ml/hr. The Model IDA-2 will accept flow rates grater than 1000 ml/hr but with much reduced accuracy.

2. The Model IDA-2 measures the flow rate from a series of volumetric measurements. In the normal flow test mode the volume sample used for the calculation varies according to the perceived flow rate and may vary within the range 0.06 - 1.0 ml. In the Hi-Accuracy Flow Test Mode the volume sample is fixed at 1.0 ml (approx). A 15-minute warm-up time from room temperature is recommended to achieve the stated accuracy at very low flow rates (e.g., <5 ml/hr); at higher flow rates, a warm-up period should not be necessary.

3. Infusion device accuracy is also affected by the compliance of the Infusion device and delivery tubes. This is because inside the Model IDA-2, water is made to rise up a tube a few centimeters. The back pressure created by this small head of water will cause some of the flow to be diverted into the compliance of the infusion device. For most infusion devices, the effect is trivial (less than 0.5%), but with very soft connecting tubing and large air pockets in the device or tubing it could be significant. The tubing between the infusion device and the IDA-2 should therefore be fairly rigid and all air should be removed before starting each flow test.

3.2.3 Derived Average Flow Rate Accuracy

As instantaneous Flowrate, see section 3.2.2.

NOTES

1. The average flow rate is derived from all of the instantaneous flow rate values and is updated after each new reading is taken. If the infusion device delivery fluctuates dramatically (e.g., with reciprocating syringe pumps that actually stop intermittently during operation) then the initial estimates of the average flow rate will change rapidly; subsequent estimates will gradually stabilize.

2. The infusion device itself will have a 'start-up characteristic' and may not achieve its set flow quickly. The operator should observe the average flow rate until it stabilizes. To achieve accurate flow rates, the infusion device should run for a while to reach a stable flow rate before the flow rate measurement is started.

3.2.4 Derived Delivered Volume Accuracy

As instantaneous Flowrate, see section 3.2.2 but subject to an additional negative error of up to 1.3 ml. This is because of the fluid which has entered the IDA-2 but has not yet been measured.

NOTE: The estimate of the delivered volume is derived from the average flow rate value calculated by the Model IDA-2 multiplied by the total time that the test has been in progress. If the flow rate is reduced rapidly or arrested for a while, then the estimated delivered volume may occasionally be revised downward.

3.2.5 Flow and Volume Accuracy Under Back Pressure

The accuracy figures from the preceding sections should be unchanged when testing under back pressure, however operators should be aware that the infusion device may react unpredictably when the back pressure is being changed.

3.2.6 Occlusion Pressure

Accuracy	**±5% of reading ± 1 LSD (least significant digit)**
Maximum Reading	**240 kPa or 36 psi**

3.2.7 Printer Interface

The Model IDA-2 uses a Centronics standard parallel interface that should work with most types of printers. (The unit is known to work with the Epson line of printers). There may be some difficulties with some types of printers with the combinations of printer-on, printer-off, and on-line and off-line conditions. Experiment with these conditions to achieve satisfactory performance of the unit's printing and non-printing modes.

3.2.8 Computer Interface

The serial port of the Model IDA-2 uses Pin 3 (signal out), Pin 2 (signal in) and Pin 7 (ground) of a 25-pin D-connector. See Figure 3.2 - Rear Panel. The Model IDA-2 delivers information at RS232 at 2400 baud, using 8 databits and 1 stop bit.

If the IDA-2 receives uppercase ASCII codes for (upper case) F, V, P, R, I, M, I then the effect will be as though the button marked with those letters had been manually pressed. (See Section 3.1.1 and Figure 3.1).

4 OPERATING INSTRUCTIONS

4.1 Setup

4.1.1 Test Fluid

The Model IDA-2 Infusion Device Analyzer is intended for use with water, saline, and may function with other low viscosity fluids used on patients. High Viscosity, oily, or extremely corrosive substances will damage the transducer system. Cleaning instructions are given in section 5.1.

NOTE: The instrument has been calibrated using tap water with a small amount of detergent added; this prevents water from sticking to the sides of the internal tubing. For best accuracy, add a small amount of detergent (e.g., 1 drop/500 ml - this should not produce foam) to reduce the surface tension.

4.1.2 Positioning the Model IDA-2 During Testing

The Model IDA-2 must be used upright on a bench or clamped to a pole. The surface of water in the drain vessel must be a least 3 cm below the outlet port.

4.1.3 Model IDA-2 and Apparatus Configuration

Figure 4.1 illustrates how the Model IDA-2 and the associated apparatus are configured.

1. Connect the infusion device to be tested to the FLUID IN port on the Model IDA-2
2. Connect one end of a drainage tube to the FLUID OUT port on the Model IDA-2
3. Connect the other end of the drainage tube to a fluid collection vessel (e.g., a 1- of 2- liter bottle or beaker).

NOTE: A short drainage tube needs to be connected to the FLUID OUT port to take waste water to a collecting vessel. If a longer drain tube is used it may cause water to siphon through the Model IDA-2 when disconnection is made at the FLUID IN port, possibly causing operating difficulties.

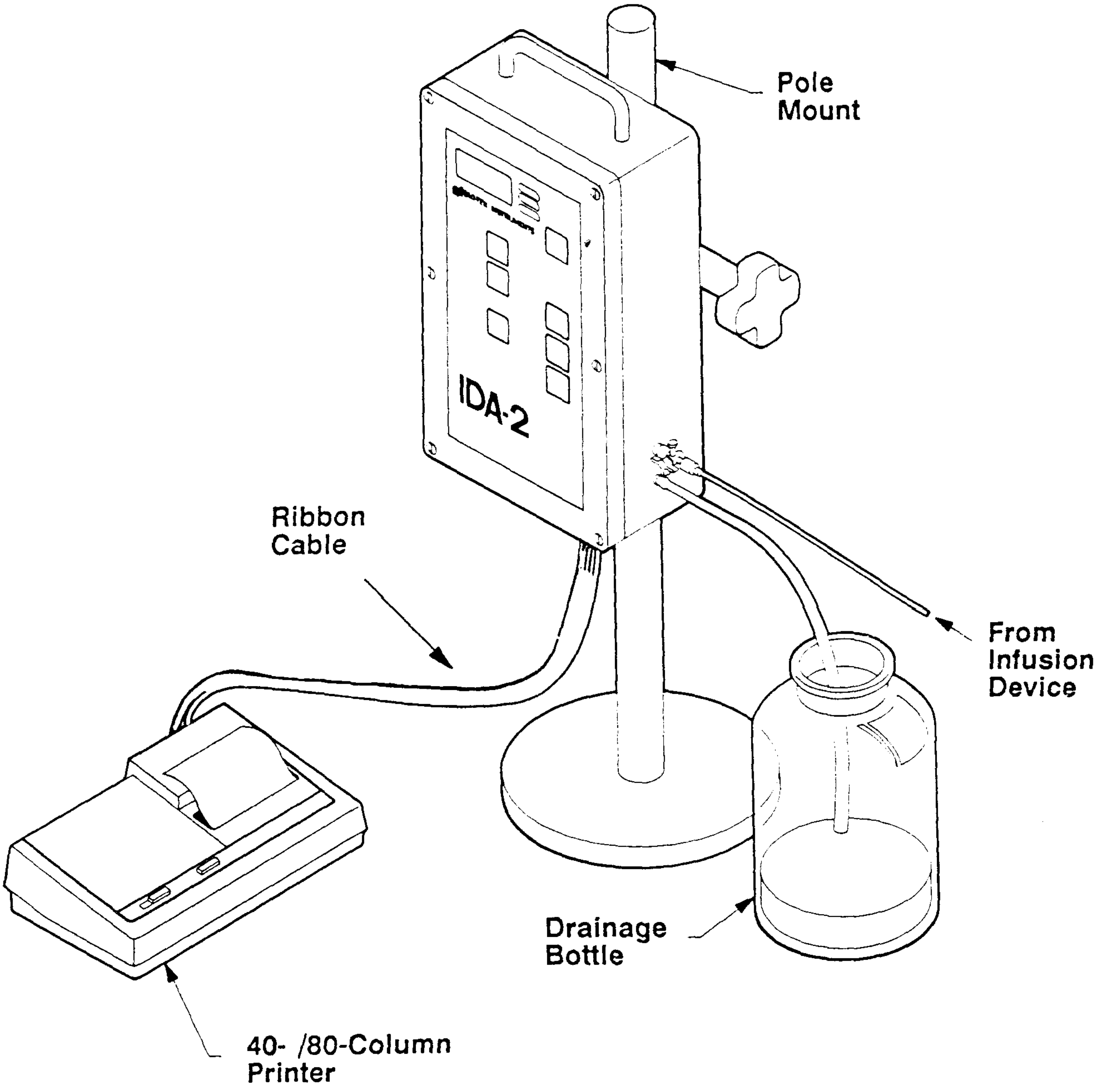

Figure 4.1 - Model IDA-2 and Apparatus Configuration

4.2 Setting the Date and Time on the Model IDA-2

The date and time within the instrument is maintained even when the instrument is switched OFF. If it is moved to another time zone, the date and time may need to be reset. The time of day figure may also need to be reset from time to time.

NOTE: This process is similar to setting the date and time on a digital watch.

1. Switch the Mode IDA-2 ON while holding down the reset button [R]

2. The display now shows the time:

   hh.mm

3. The year may be changed one year at a time by pressing [P]. A sustained press will move the counter to 90 and then rapidly forward to the correct year.

4. Similarly, the month may be displayed by pressing button [V] and changed by holding the switch down.

5. Continue with date [F], hour [H], and minute [M] as in the preceding steps.

6. Between selections the display will revert to:

   hh.mm

7. Switch the unit OFF.

8. Check the results by repeating the preceding steps without changing readings.

NOTE: during the above clock set routine, seconds may be set to zero by pressing [I], but this also advances the instrument to the operating mode.

4.3 Initial Priming Sequence

When the instrument is first switched ON, the software is required to check and store a number voltages from inside the transducer unit and to establish reference values. To assist with this procedure, the operator is required to flush through with air (e.g., 20 ml) before switching the unit ON and with water (5 to 20 ml) afterwards. The recommended procedure is as follows:

1. Inject (infuse) at least 20 ml of air into the Model IDA-2 from a syringe. This is to clear excess water from the mechanism.

2. Switch the unit ON and wait until the prime legend appears and the printer (if connected) stops:

--P-

3. Inject water from a 5 or 10 ml syringe (or with the infusion device to be measured). A steady rate is important; 0.5ml/sec would be satisfactory. The internal solenoid audibly clicks once or twice before the display begins to flash, indicating that it is now properly set up and is checking for bubbles. Continue infusing until the flashing stops. After this procedure the display shows:

----

4. If the priming procedure fails (after more than 10ml has been injected), the beeper sounds and this entire procedure must be repeated.

Note: Once the initial prime sequence is completed it will not need repeating until the instrument is next switched ON.

Incorrect operation after successful priming is most likely to be caused by bubbles or by flooding (internal air replaced by water). In either case press reset [R] and inject 10 ml air followed by 2-3 ml water from the infusion device. Also refer to section 7.4 on troubleshooting information concerning priming.

4.4 Connecting and Changing the Infusion Device

1. After the initial priming, and also when changing or reloading the infusion device, the FLUID IN connector will be opened.

NOTE: In this case blow out excess water using a 10ml air filled syringe. Then connect the (next) infusion device and deliver 2-3 ml of water before entering the flow test.

2. The use of a 3-way tap at the <u>FLUID IN</u> port should eliminate such problems during disconnections and may also be used to provide a source of priming water if the infusion device reservoir is very small (e.g. for a small syringe pump). See Figure 4.2 for recommended priming apparatus for pumps with very small reservoirs or very low maximum flow rate.

3. A brief summary of operating procedure is shown on Fig. 4.3

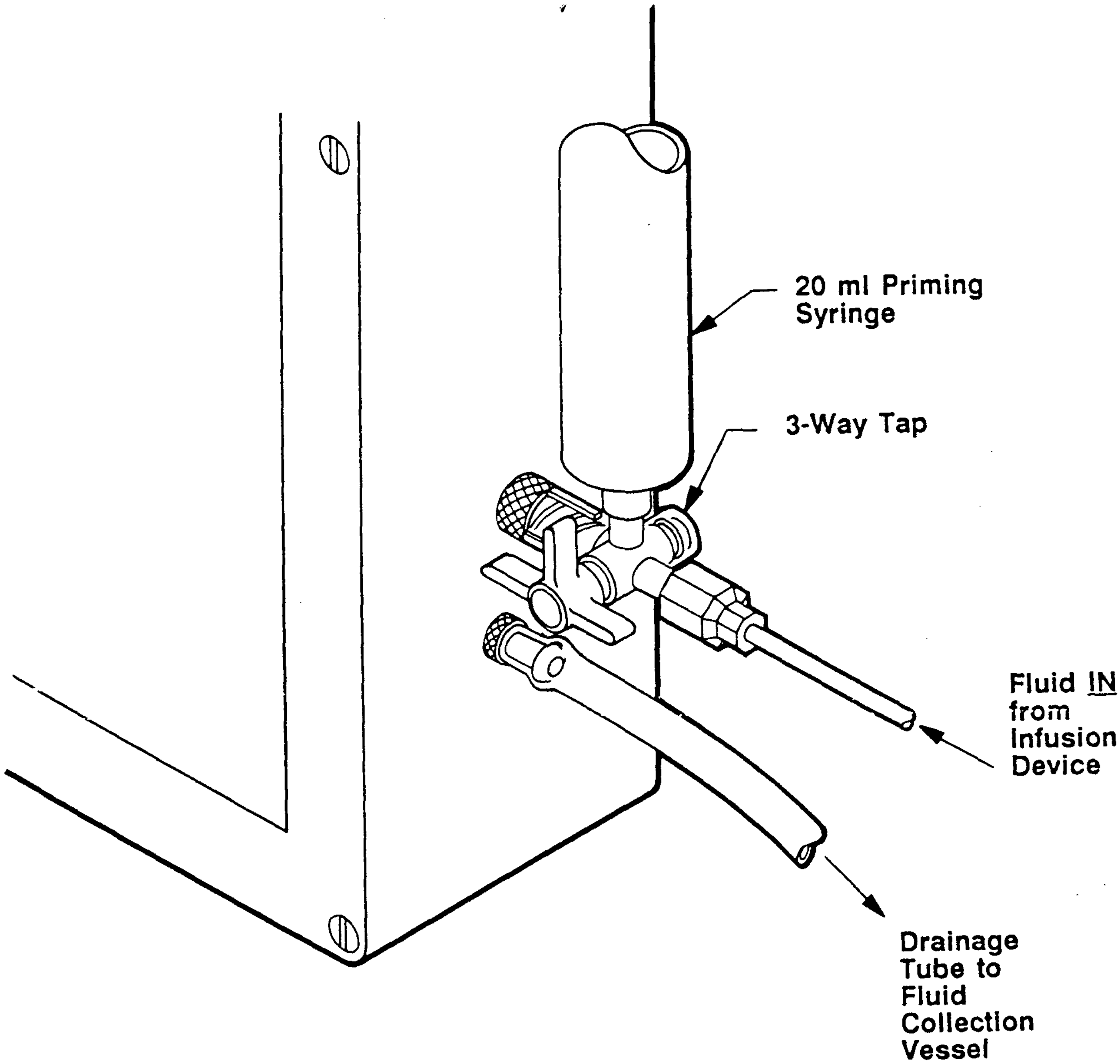

Figure 4.2 - Priming Apparatus for Pumps with Small Reservoirs or Low Maximum Flow Rates.

IDA-2 BRIEF OPERATING INSTRUCTIONS

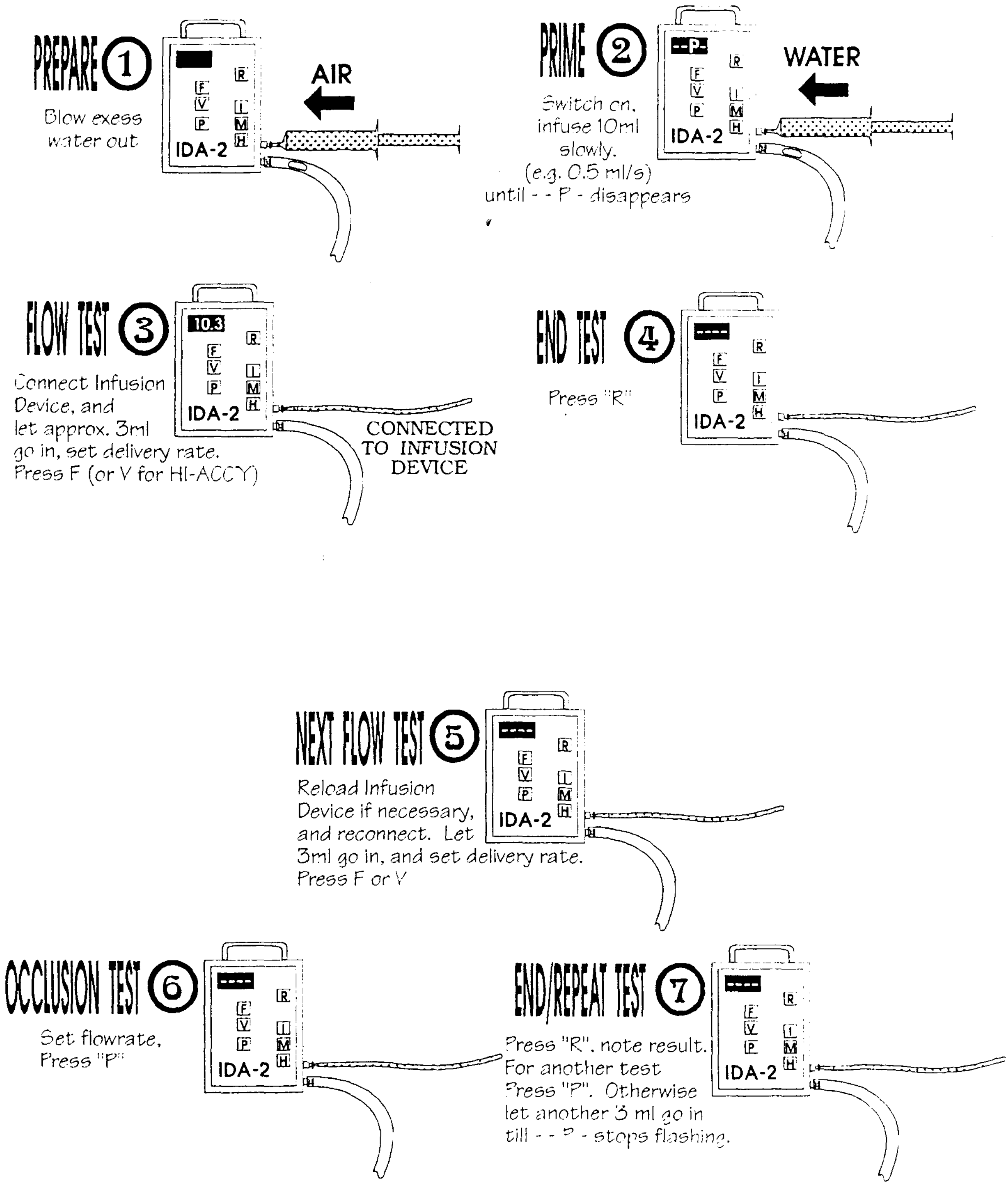

Figure 4.3 - Summarized Operating Procedure

4.5 Flow Rate and Volume Tests (Normal Mode)

1. Set the infusion device to the desired flow rate and the volume to be measured (if this feature is available).

2. Start the infusion device.

3. Press [F] on the IDA-2 for the flow rate test. The first measurement should appear within 30 seconds (longer for very slow flow rates). At 1ml/hr this should take approximately 5 minutes. When a flow rate is obtained, this will be held on the display until the next value is obtained. The process is then repeated indefinitely.

4. At any time the derived average flow rate can be displayed by pressing [F] a second time.

   Note: Repeated pressing of button [F] causes the display to alternate between current *(instantaneous)* flow rate and average flow rate.

5. Press volume test [V] to view the derived cumulative delivered volume.

6. Press reset [R] to stop the flow test.

7. Printed results can be obtained if a printer is connected. Select the desired print frequency by pressing immediate repeat [I], 5 minutes [M], or 1 hour [H].

8. Typical printed results are shown in Figure 4.4.

NOTES:

1. **Sample Volume:** The derived cumulative volume on the printout in Figure 4.4 shows that each measurement is made using a sample of approximately 0.1ml. If the flow rate rises above about 45 ml/hr this changes to 0.3ml, and above 110 ml/hr (approx.) to 1.3ml.

2. **Bubbles:** Air bubbles passing through the flow measurement system may cause inaccurate results. A number of program features are included to detect bubbles and apply corrections to the results; however, it is recommended that the operator ensures that the infusion system is free from air at the start of the flow measurement. If bubbles are seen or suspected, press reset [R] and infuse an additional 2 to 3ml of bubble free water before continuing.

```
*  FLOW TEST *
* 19:20:07  02-JUL-92
        Set Flowrate:..30 ml/hr.
                    --- DERIVED ---
Time      Inst Flow Av Flow Cum Vol Run
hh:mm:ss   ml/hr    ml/hr    ml
19:20:07                     0.0
19:20:47   30.38    30.38    0.3    01
19:21:01   29.94    30.16    0.5    02
19:21:15   29.74    30.02    0.6    03
19:21:29   29.82    29.97    0.7    04
19:21:44   29.39    29.85    0.8    05
19:21:58   30.10    29.89    0.9    06
19:22:12   29.74    29.87    1.0    07
19:22:26   29.54    29.83    1.2    08
```

Figure 4.4 - Typical Printed Outputs

3. If cold tap water is used and the flow-rate is slow, there may be some release of air from the water as it warms in the infusion reservoir, tubing, or within the IDA-2. This can be avoided by using water at room temperature or using cooled water from the hot tap (i.e. partially degassed). Full degassing is recommended if overnight running is contemplated.

4. If a flow rate in excess of 1000ml/hr is detected, the Model IDA-2 causes the beeper to sound twice and 2 question marks (??) to appear at the end of the print line. Usually the IDA-2 will continue to take readings.

4.6 Flow Rate and Volume Tests (Higher Accuracy Mode)

Initiating the flow test using the 'Higher Accuracy Mode' (button [V]) causes all measurements to be made with a sample volume of 1ml (approx). This gives higher accuracy results for all flow rates below 110ml/hr but at the expense of longer times between readings. However the time to first reading is unchanged.

The form of results in this mode is shown in Figure 4.5. The first two readings are for indication only, and **are not used** in the calculation of average flow rates and volumes. On the print-out these items are marked with a 'P' (for provisional) at the end of the print line. For flow rates above 50ml/hr these provisional results are not printed.

* HIGHER ACCURACY FLOW TEST *
* 16:38:19 02-JUL-92
Set Flowrate:..30 ml/hr
--- DERIVED ---

Time	Inst Flow	Av Flow	Cum Vol	Run
hh:mm:ss	ml/hr	ml/hr	ml	
16:38:19			0.0	
16:38:59	30.80	30.80	0.1	00P
16:39:21	30.15	30.15	0.2	00P
16:40:47	29.81	29.81	1.2	01
16:42:54	30.33	30.07	2.3	02
16:45:00	30.57	30.24	3.4	03
16:47:08	30.29	30.25	4.4	04
16:49:17	29.91	30.18	5.5	05
16:51:27	29.51	30.07	6.6	06
16:53:38	29.59	30.00	7.7	07

Figure 4.5 - Form of results in Higher Accuracy Mode

When in the Higher Accuracy Mode, the IDA-2 display shows an 'H' in the first position on the display, e.g.

$\boxed{\text{H13.1}}$

4.7 Average Flow Rate

This is calculated from the current (*instantaneous*) flow rate values. Accuracy and time to establish a stable average will depend on the pulsatility of the infusion device being tested. Examination of the current or *instantaneous* flow rate readings in relation to the derived averages will give the user an idea of the reliability of the results.

NOTES:

1. <u>It is advisable to start the flow test when the infusion device has been running for a short time</u>. This is because infusion devices do not reach their set flow rate immediately. One or more reading at the start may therefore be low and if these readings are included in the average flow rate calculation then the derived average flow rate will be (correctly) below the set rate on the infusion device.

2. The method of calculation of average flow rate used in the IDA-2 is given in Section 6.2.

4.8 Derived Cumulative Volume Delivered

The Model IDA-2 Infusion Device Analyzer derives the cumulative volume delivered from the flow rate information. Volume delivered is also recorded by the printer. The derived cumulative volume can be viewed at any time during a flow test by pressing button [V].

Note 1: The cumulative volume figure is calculated by multiplying the derived average flow rate by the total time elapsed since pressing the flow or volume test buttons.

Note 2: When the infusion device stops, the IDA will be part way through a measurement cycle, and therefore the final Cumulative volume reading will be slightly low. At high flow rates, and in the Higher Accuracy Mode, the deficit due to this effect could be up to 1.3ml.

4.9 Occlusion Pressure Test

After the initial priming, or after pressing reset [R], the occlusion test may be initiated by pressing [P]. This occludes the <u>FLUID- IN</u> port and shows the pressure generated by the infusion device. The display of pressure can be alternated between **psi** and **kPa** by repeated pressing of button [P].

The pressure should rise steadily until:

1. The infusion device stalls, or
2. The infusion device alarm sounds and flow is automatically stopped, or
3. A pressure of 240kPa (36psi) is reached.

If a printer is on-line, this will record sequential pressure measurements next to the time of each measurement, as shown in Figure 4.6.

When the occlusion test is completed, the peak pressure reading will be recalled on the printer and will also show briefly on the display as a flashing number.

After the occlusion test has been completed the display will show a flashing [--P-] requiring infusion of 3-4 ml of extra priming water. Continue infusing for a few seconds after the flashing stops. However, if the next test is to be another occlusion test, then it is not necessary to wait for the flashing [--P-] to stop before proceeding.

Note: The IDA-2 does not measure the size of the 'bolus' of fluid released after the occlusion is cleared. However a simple bolus test may be incorporated into the Bolus test procedure incorporated into section 4.14.

```
* OCCLUSION TEST *
* 18:53:49  02-JUL-92
          Set Flowrate: 120 ml/h
Time              Pressure
mm:ss     kPa   lb/sq in   mmHg
00:00     00     0.0        00
00:02     16     2.3       120
00:04     40     5.8       300
00:06     67     9.7       503
00:09     97    14.1       728
00:11    128    18.6       960
00:14    158    22.9      1185
00:16    177    25.7      1328
00:19     33v    4.8       248
* PEAK VALUE -
00:18    186    27.0      1395
```

Figure 4.6 - Sample Printout from Occlusion Test

4.10 Reset Button [R]/PRINT Header

When satisfactory results have been obtained, the analyzer may be returned to an inactive condition by pressing the START/RESET button [R]. In some cases it may be necessary to wait for the printer to finish before RESET is effective.

Pressing [R] a second time will cause the printing of a new header strip for the next infusion device to be tested. This is identical to the header which appears when the IDA-2 is first switched on - see Figure 4.7 - Sample Header Printout.

```
* BIO-TEK INFUSION DEVICE ANALYZER *
          Model IDA - 2
                                      Program Version
* 16:19:23  02-JUL-92      (6.0/6332)
                                      IDA Transducer Number
Control No   :_ _ _ _ _ _ _ _ _ _
Serial No    :_ _ _ _ _ _ _ _ _ _
Model No     :_ _ _ _ _ _ _ _ _ _
Manufacturer :_ _ _ _ _ _ _ _ _ _
Location     :_ _ _ _ _ _ _ _ _ _
```

Figure 4.7 - Sample Header Printout

4.11 Printer and Computer Facilities

Printer Port

The Model IDA-2 senses the connection of a printer via the Centronics interface connector *busy line*. If no printer is connected, the analyzer will still function normally.

If a printer is connected, switched ON, and is on-line, then the IMMEDIATE REPEAT LED will show. In this condition, the measurements of flow rate, volume, or pressure are printed in succession. For longer tests, the printer may only be required to print at intervals. Intervals of approximately 5 minutes or 1 hour (e.g. 5 minutes + time for one measurement) can be selected by pressing [M] or [H] respectively. When delayed printing is selected, there is a blank line between readings to show they are not consecutive (see Figure 4.8).

If the flow ceases during a period when the printer is set to repeat every 5 minutes or every hour, the last reading will be recalled on the printer when the reset button [R] is pressed.

```
          Set Flowrate:........
                     --- DERIVED ---
Time      Inst Flow Av Flow Cum Vol Run
hh:mm:ss    ml/hr    ml/hr    ml
19:30:01                      0.0
19:30:41    31.41    31.41    0.3     01

19:35:45    29.82    30.31    2.9     23

19:40:54    30.47    30.17    5.5     45

19:45:59    31.41    30.27    8.1     67

19:51:10    30.80    30.48   10.7     90

19:56:19    30.51    30.65   13.4    113
Last reading:-
19:57:13    31.72    30.69   13.9    117
```

Figure 4.8 - Sample Flow Strip with Delayed Printout

The delayed print feature is useful for long term tests overnight or over a weekend with slow flow infusion devices.

Note:

1. The print repeat rate can be altered at any time, and if the printer is connected, or disconnected during a measuring cycle, this change will be detected. If the printer is disconnected while the printer is printing the IDA program may hang. If this happens switch the printer back on-line and wait for the printing to be completed.

2. At high flow rates (e.g. 1000ml/hr the printer must complete each line of print sufficiently quickly to be ready to receive the next reading (less than 5 seconds between readings at high flow rates). A very slow printer may thus cause the IDA-2 to fail. The problem can be solved by using a faster printer, or by using the 5 minute print facility (button [M]).

Computer Port

The Model IDA-2 sends information to the computer port which is essentially the same as sent to the printer. However, there are some differences:

1. All flow measurements are sent to the computer irrespective of the setting of the Print Repeat settings.

2. The print strip headers (Infusion Device Details, Flow Test, Occlusion Test) are sent to the computer in abbreviated form.

3. The printer and computer information is sent at different times. When measuring slow flow rates there can be considerable delays between information being printed and sent to the computer.

4. On Occlusion test, results are sent to the computer much more frequently than to the printer.

When using the computer port linked to a computer, communication is in RS232 format using pins 2,3,7 (2 = signal in, 3 = signal out, 7 = ground). With this configuration the RS232 lead will **not require crossover** of lines 2 and 3. The communication protocol is 2400 BAUD, no handshake, 8 data bits, 1 stop bit **(2400,N,8,1)**.

The computer link can be used to store or print records by computer, or used with the "GRAPHICS CAPTURE PROGRAM" available as a companion to the IDA-2. This program provides graphical display of test results and facilities for manipulating and storing the test records.

Version 2 of the GRAPHICS CAPTURE PROGRAM is designed to work with the IDA-2 to allow control of the IDA-2 from the keyboard of the computer. The IDA-2 will respond to the transmission of upper case ASCII characters F,V,P,R,I,M,H. The results will the same as would be achieved by pressing the IDA-2 buttons marked with these letters. Users can employ this bi-directional capability from other programs able to send the above characters in the correct communication protocol (above).

4.12 Testing Specific Types of Infusion Device

4.12.1 Motorized Syringe Pumps

Description of Device

Syringe pumps usually take a disposable plastic syringe, which may be obtained from a variety of manufacturers, and are used for the slow delivery of drugs in the range 0.5ml/hr or less to 500ml/hr.

Flow rate is usually fairly steady, the syringe being driven by a 'lead screw' attached to a gear train and a synchronous motor, or a stepper motor. The effect of single steps of the motor can sometimes be seen at slow flow rates, and a few syringe pumps have a flow rate pattern which cycles above and below the set rate. These cycling pumps can only give the correct average flow rate on the completion of an integer number of cycles.

Some syringe pumps have the facility for Patient Controlled Analgesia by which the patient can press a button to cause the delivery of a quantity of a pain relieving pharmaceutical agent. The flow rate in these cases may be very high, but with the total quantity allowed in a given period restricted by the program.

The Syringe

Some manufacturers specify a particular type of syringe, and this may be specially made for the particular pump. However, many manufacturers recommend a particular or range of disposable syringes which are widely available. Most common single use syringes are designed to be used once (one stroke) by hand, and are not ideal for use in syringe pumps. The plunger is lubricated sufficiently for the single use but thereafter may become very stiff. The plunger and barrel are often flimsy in construction and will buckle if the plunger sticks or if an occlusion occurs. If this happens the flow rate and occlusion pressure performance may be seriously affected by the syringe.

For important measurements, a new syringe should be fitted before each test.

Performance Specifications

Manufacturers' performance specifications for syringe pumps (e.g. flow rate accuracy) may omit errors due to the variability in the behaviour of the syringe, and also may not fully explain the 'start-up' characteristic. Hand syringes, though often well made, are not required to meet very high standards for volume delivered (e.g. 4% of markings). This needs taking into account when assessing accuracy of syringe pumps using the IDA-2.

When a syringe pump (or any other form of infusion pump) is started, no fluid is delivered until all the slack in the mechanism has been taken up, and the back pressure (caused by the plunger friction and actual fluid back-pressure) has been overcome. Therefore, the pump will not reach its set flow rate for some time. At very slow flow rates (e.g. 1ml/hr) this may be 30 minutes or more. The set

flow rate on the pump must therefore be regarded as the 'eventual flow rate' or 'mid-stream flow rate'.

Flow Rate Measurements

The IDA-2 measures the overall average flow rate which is ideal for assessing the expected performance of the pump in the clinical situation in which the Infusion Device is usually set running from a standing start. The true (overall) average flow rate is thus the total volume actually delivered divided by the time taken.

However, users of the IDA-2 may prefer to compare the eventual flow rate with the set rate. To do this the pump must be started first, and the IDA-2 flow test only started when about 1ml or more, should have been delivered by the pump (estimated from the time since starting, and the set flow rate).

The difference between these two average flow rates may be illustrated in Figure 4.9.

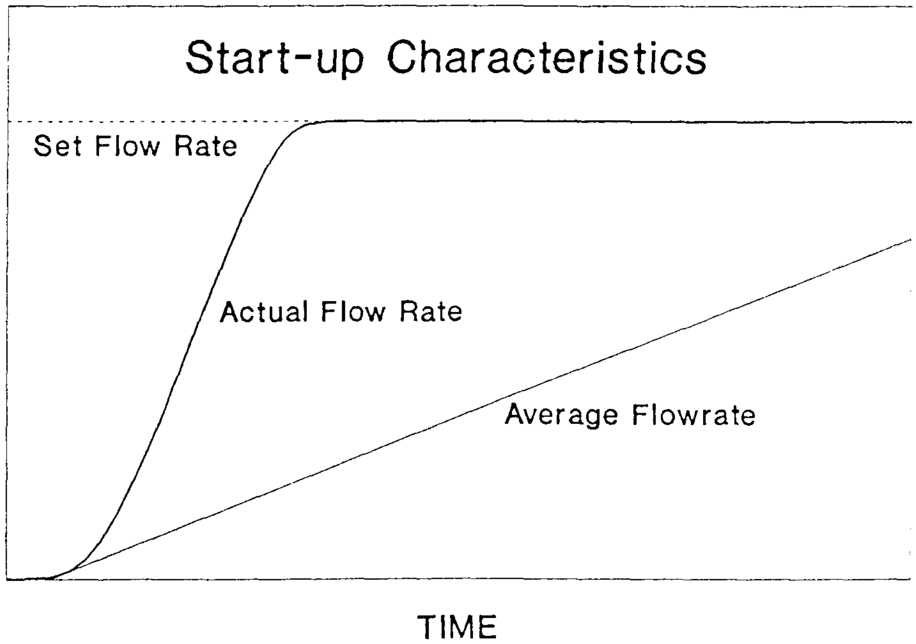

Figure 4.9 - Syringe Pump Start-up Characteristic and the Effect on Overall Average Flow Rate

Occlusion Test

Some syringe pumps can deliver very high pressures on occlusion. Others have a pressure limiting device either sensing back-pressure via the syringe plunger, or in an external pressure balloon which is fitted in a pressure sensing device after the syringe.

4.12.2 Volumetric Infusion Pumps

Volumetric pumps are those which can deliver fluid from a bag or bottle and which do not rely on a count of drops falling through a drip chamber, other than as a secondary check. The volumetric delivery device may be one of several types. Mostly they produce unsteady flow:

1. Moving finger peristaltic action on a soft tube.
2. Rotating rollers on a soft tube.
3. Reciprocating piston devices with the pistons inside or outside the fluid circuit.
4. Special pulsing cassettes built into the disposable circuit.

For notes on Moving Finger and Rotating Roller types see section 4.12.3 on **Peristaltic Pumps.**

Reciprocating piston pumps normally include a special bi-directional syringe (cassette) which fits into the instrument and is driven by a cam. When primed, the cassette normally delivers fluid at a fairly steady rate, then the syringe plunger reverses, drawing new fluid from the bag at a high rate. During this latter phase, **no flow is delivered.** The pump calibration takes account of the time taken to draw in new fluid, so that higher than the set flow is recorded during pumping to allow for the period of no-flow during refilling. At high flow rates the fluctuations in flow rate may be considerable.

When testing flow rate on such pumps, the recorded flow will cycle above and below the set rate, but the average flow result should gradually approach the set rate over a number of pump cycles. At high flow rates (e.g. 400-1000ml/hr) such pumps may have a very erratic flow rate pattern, delivering fluid in spurts of up to 2000ml/hr. The infusion device analyzer is designed to measure flow rate up to 1000ml/hr and therefore cannot deal with such flow patterns at the higher flow rates.

> **The pulsing pump types do not deliver at a flow rate which can be measured, and also there may be long delays between pulses. The IDA will not produce accurate flow rates for such devices although at higher flow rates and in the Higher Accuracy Mode (the IDA-2 then measures over a larger volume sample e.g. 1ml) the accuracy should be within 10%.**

To test volumetric pumps at high flow rates over long periods it may be useful to connect the fluid outlet of the IDA to drain into the fluid reservoir for the infusion device, so that the same water can be pumped round indefinitely.

The accuracy claims for the IDA-2 should be correct for instantaneous flow rates up to 1000ml/hr, but the average flow rates and cumulative volume figures, which are derived from the instantaneous flow rate measurements may be less accurate with infusion devices which actually stop for part of the time. Users

should experience the testing of a variety of infusion devices to achieve a better appreciation of the meaning of IDA test results with different pulsatile pumps or 'stopping' infusion devices.

* FLOW TEST *
13:14:38 02-JUL-92
Set Flowrate:.500 ml/hr

Time hh:mm:ss	Inst Flow ml/hr	--- DERIVED --- Av Flow ml/hr	Cum Vol ml	Run
13:14:38			0.0	
13:14:57	509.1	509.1	2.7	01
13:15:09	818.4	627.3	5.4	02
13:15:17	543.2	596.8	6.5	03
13:15:31 *	316.7	488.3	7.2	04
13:15:39	668.9	516.4	8.7	05
13:15:50	506.0	514.2	10.1	06
13:16:02	818.7	543.6	12.7	07
13:16:12	508.5	538.2	14.1	08
13:16:26 *	338.6	505.1	15.0	09
13:16:34	585.4	512.4	16.5	10
13:22:35 *	332.6	500.2	66	43
13:28:44 *	309.7	494.3	116	77
Last reading:-				
13:31:26	810.6	494.7	138	92

Figure 4.10 - Example Test Strip for Volumetric Pump

Note the low readings (*) when the cassette reprimes.

4.12.3 Peristaltic Pumps

Peristaltic pumps usually work by forcing a bolus of fluid forward in a soft tube by occluding the tube between rollers or a set of 'fingers' operated by cams. The flow is thus unsteady, moving above and below the rate set, and often flow reverses for part of the cycle.

The rate of forward movement of the bolus may be controlled by the rate of movement of the rollers or cams, and on some pumps this may in turn be controlled by the rate of drops falling in the tubing 'drip chamber' using a photo-electric sensor (see section 4.12.4 on drop-counting pumps and controllers).

The flow rate will be cyclic, and on some pumps, may be zero for long periods while the cumulative drop count is corrected, or in the case of some 'bolus' feeding pumps, according to a preset program.

In both cases the IDA-2 will show the present flow rate, while the derived average flow rate and cumulative volume displayed or printed should gradually approach the set rate, if the pump is working properly. Accuracy of the estimated average flow rate and delivered volume will be lower for infusion devices which stop for part of the time.

The stall pressure of gastric feeding pumps will sometimes be very low. Flow rate is also often temperature dependant.

```
* FLOW TEST *
11:42:09 02-JUL-92
     Set Flowrate:..100 ml/hr.
                     --- DERIVED ---
Time      Inst Flow Av Flow Cum Vol Run
hh:mm:ss   ml/hr     ml/hr    ml
11:42:10                      0.0
11:42:45    81.1     81.1     0.8    01
11:42:58    82.2     81.9     1.1    02
11:43:06   159.0     97.6     1.5    03
11:43:19   161.7    108.4     2.1    04
11:43:33   146.8    114.1     2.6    05
11:43:46    80.5    106.4     2.8    06
11:43:59    80.8    102.3     3.1    07
11:44:13    80.9     98.2     3.4    08
11:44:26    81.4     96.3     3.6    09
11:44:34   152.6    100.8     4.0    10
11:44:47   161.7    103.3     4.5    11
11:45:00   154.8    106.4     5.0    12

11:51:01    80.7    100.4    14.7    41
Last reading:-
11:52:15   154.3    100.2    16.8    47
```

Figure 4.11 - Test Strip for a Peristaltic Pump

4.12.4 Drop-Counting Pumps and Controllers

These devices attempt to control the infusion rate by detecting the quantity of fluid delivered from the number and rate of drops passing through the drip chamber on the 'giving set'. The drops are usually detected as they pass through a photo-electric gate clipped onto the drip chamber.

In drop-counting pumps the active element is usually a peristaltic pump of the cam-operated moving finger type, and these can infuse against high back-pressure, provided the occluded section of the infusion tubing is relatively new. Infusion controllers have no pump, so that the maximum back- pressure which can be applied is limited by the height of the fluid bag. Infusion is normally controlled by the opening and closing of a gate-clamp on the infusion tubing. Thus a bolus of fluid is allowed through, the drops delivered are counted and the gate is closed until the number of drops delivered agrees with the drop-rate set. The gate is then re-opened and the process is repeated. Flow rate is therefore unsteady, and may be zero for part of the time.

With drop-counting pumps and controllers, the operator sets the drop rate to achieve the desired infusion rate. This is done by using the figure for drops/ml printed on the 'giving set' or its container. This drops/ml figure can vary (e.g. from 15 drops/ml to 60 drops/ml) for different giving sets. Also the temperature, fluid viscosity, surface tension, and drip rate will affect the result.

Since the objective is to achieve a particular flow rate in ml/hr, the IDA-2 bypasses these uncertainties by measuring and recording the actual flow rate delivered.

The stall pressure will be very different for pumps and controllers, and in the case of controllers, it will show the pressure head applied by the bag and 'giving set'. This will usually correspond to a level just below the bottom of the bag.

Accuracy of the derived average flow rate and delivered volume will fall off at higher flow rates, particularly if the fluid source is not mounted high above the IDA. It is recommended that the fluid source is mounted at least 1.5 meters (4' 10") above the IDA-2. Quoted accuracy will only be achieved with infusion devices which provide continuous flow.

4.13 Measuring Flow-rate against Back-pressure

Safety and performance standards for infusion devices expect manufacturers to state the flow characteristics under specified back-pressure conditions. For instance, the flow rate might be quoted at zero output pressure, then subjected to back pressure of +300mmHg, and then -100mmHg. Some infusion devices (e.g. gastric feeding pumps) will not need to perform well against high back pressure, whereas other types (e.g. intravenous feeders) must deliver the stated flow rate against some back pressure.

The IDA-2 can be subjected to back pressure within the range +300mmHg to -100mmHg to test the effect on delivered flow rate. Back pressure in this range will not affect flow measurement. Back pressures outside this range are not recommended.

The following test arrangement is suggested for performing flow rate tests under back pressure. The pressure at the IDA-2 outlet must be returned to zero before performing an occlusion pressure test, and when changing infusion devices.

The recommended procedure is as follows:

1. Perform an initial prime.
2. Set outlet reservoir pressure to zero (open to air)
3. Blow AIR through the IDA with a large syringe to ensure that there is practically no water in the outlet tube.
4. Connect the IDA-2 to the infusion device to be tested.
5. Pressurize collection vessel to highest required (positive) test pressure.
6. Allow infusion device to deliver at least 3ml.
7. Conduct flow measurements.
8. Reduce pressure in collection vessel to next test value.
9. Repeat steps 6 and 7 as required.
10. Release pressure from collection vessel before disconnections are made. Remember that disconnecting the circuit under pressure may cause explosive release of water.

See Figure 4.12 for a suggested apparatus for back pressure testing

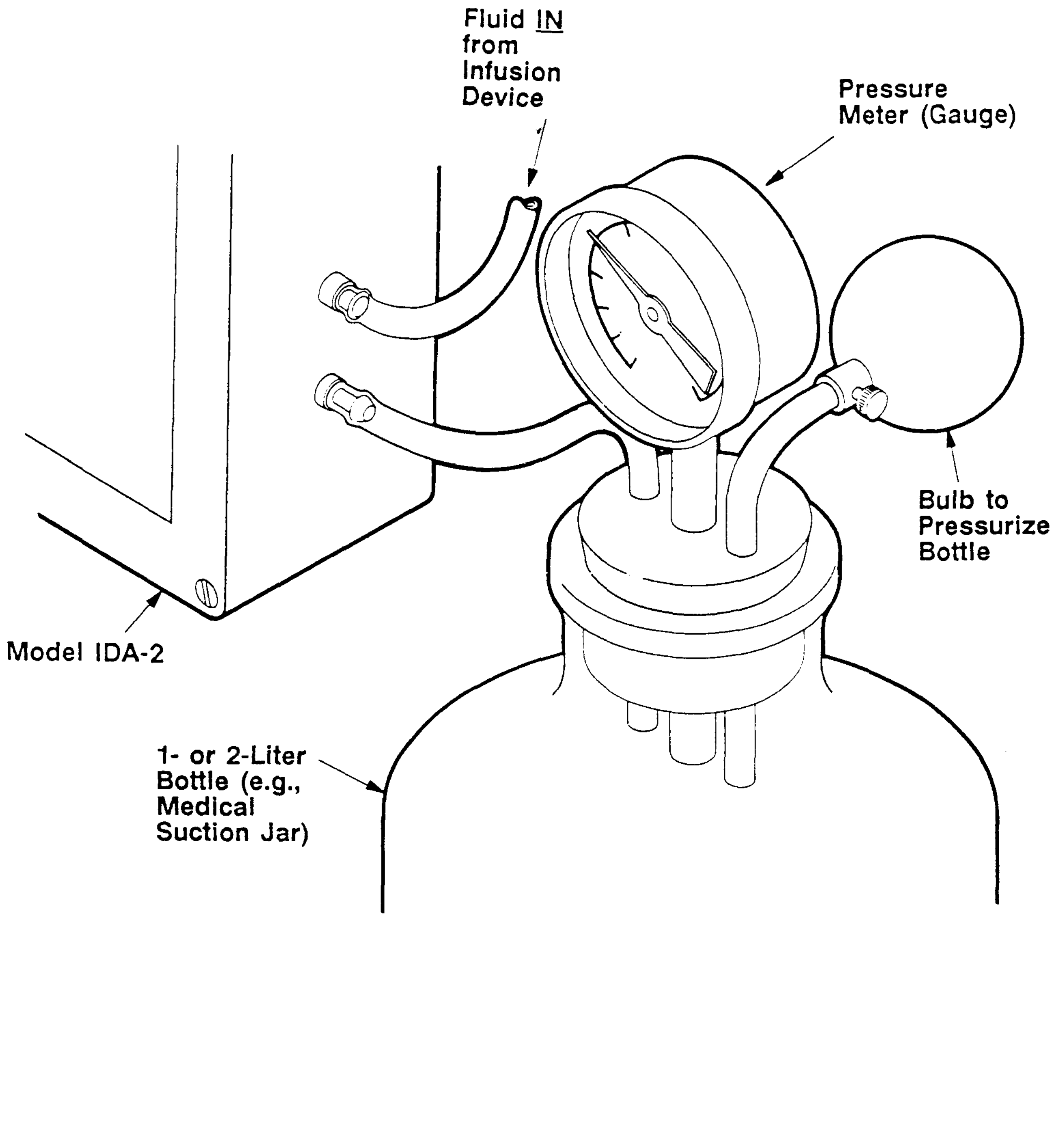

Figure 4.12 - Setup (suggested) for Flow Rate Measurement with Variable Back Pressure

4.14 Bolus Measurement

When an infusion tube becomes blocked, the pressure will rise due to the pumping action (in the case of pumps), or the height of the reservoir (in the case of controllers). Infusion against back pressure is necessary in some situations to overcome arterial pressure, or to force fluid through a small needle. However, excessive pressures are undesirable and many infusion devices include an alarm circuit to arrest fluid delivery if a preset pressure is exceeded. Some other devices simply stall at a safe pressure. The IDA is able to measure and record the pressures which are developed during an occlusion.

Apart from the pressure reached during an occlusion, there is another parameter which has important safety implications. The size of the 'bolus' of fluid released suddenly when the occlusion is cleared may cause damage at the injection site, or more seriously, in the case of short half-life pharmaceuticals being infused at a slow rate, the bolus may represent an excessive dose.

Measurement of the bolus volume requires some thought and depends partly on the infusion tubing, other circuit components, the set flow rate, and the pressure existing when the obstruction is cleared. There are two bolus figures which are worth knowing.

1. **Bolus in the alarm condition.**
   If the infusion device signals an occluded infusion line, the operator will deal with the cause of the occlusion, thus releasing the bolus (BOLUS 1). Pumps often deliver a bolus of 1-2ml, whereas controllers deliver much less. Some modern pumps have a program to back-off the applied pressure when the occlusion alarm sounds to reduce or eliminate the bolus.

2. **Bolus is released before the alarm sounds.**
   The pressure build up will sometimes clear the blockage or kink in the infusion circuit, thus releasing the bolus (BOLUS 2). This is very hard to avoid, and the volume of the bolus depends on the pressure existing at the time of clearance.

Thus there is a need to define what is meant by bolus, and we suggest the above definitions of:

BOLUS 1 That delivered in the alarm condition.

BOLUS 2 That delivered before the alarm condition at or close to the alarm pressure.

We suggest the following physical arrangement and procedure (See Figure 4.13)

1. Attach a 3-way tap at the FLUID-IN port on the IDA-2 with the upper limb connected to the barrel of a 2ml syringe.

   Note: Operate the tap to allow enough water into the syringe to reach the calibrated section of the barrel.

2. Then conduct an occlusion test in the normal way for the IDA-2, but when the infusion device alarms, turn the tap to connect the infusion device to the syringe, and note the rise in level of water in the syringe. This is BOLUS 1. Note the peak pressure achieved from the IDA-2 print strip.

   Note: Make sure the tap is set to connect only the infusion device to the syringe for the bolus measurement, and not the IDA as well, so that the bolus measured is not affected by the internal compliance of the IDA-2.

3. Repeat the procedure, but test the bolus just before the pressure reaches the previous peak pressure. This is BOLUS 2.

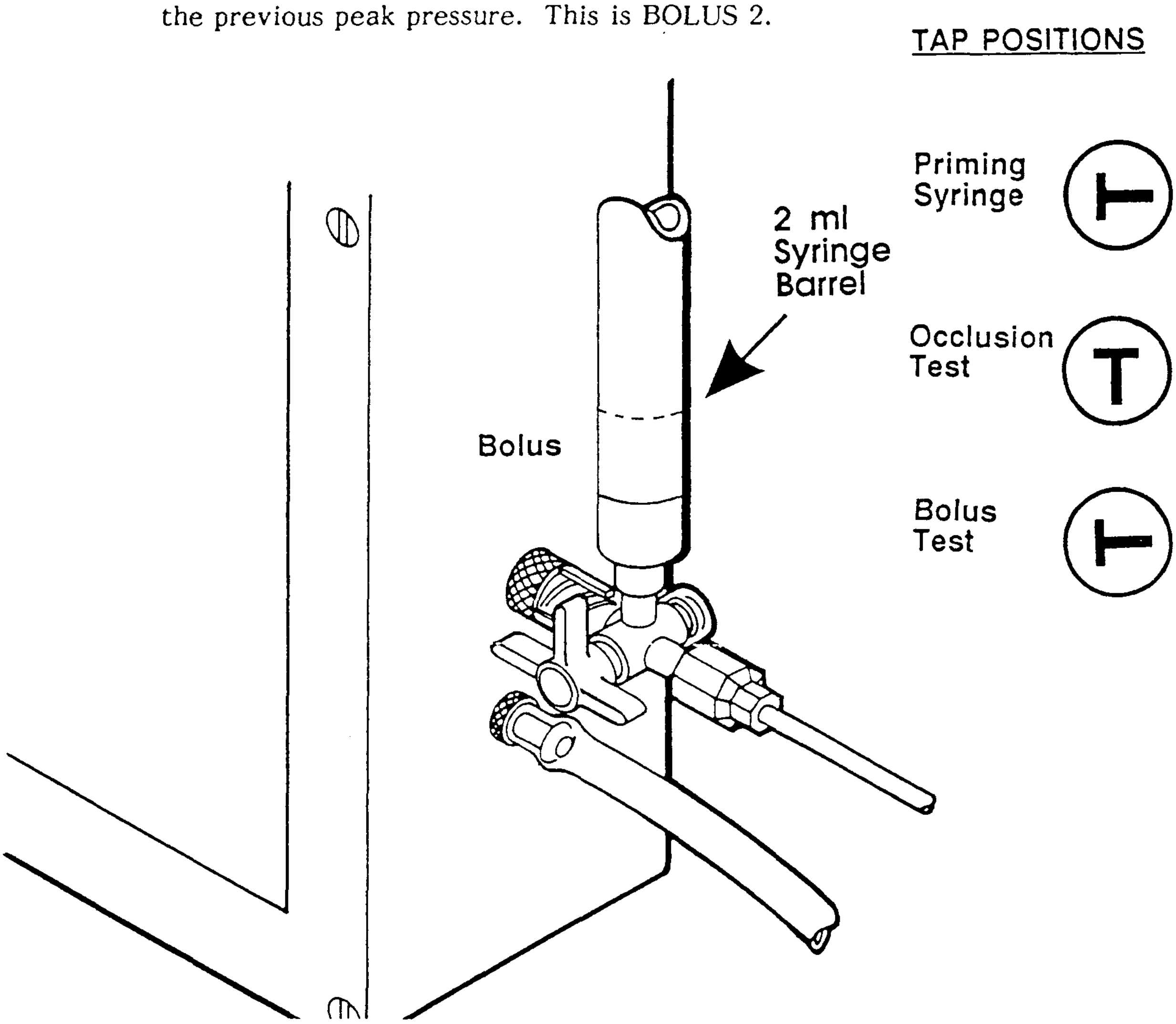

Figure 4.13 - Test Set-up for Bolus Measurement

5 Maintenance Service and Calibration

5.1 User Care and Maintenance

Storage
Do not leave water inside the unit when storing or shipping. At the factory, units are 'dried' before shipping by connecting a suction pump to the FLUID OUT connector for 5 minutes with the IDA operating in the 'Lamp Test' mode (see section 7.2). Connection to a medical suction pump will not harm the IDA.

Handling
The equipment will be damaged if dropped or subjected to excessive shock.

Use
For best performance the IDA-2 should be regularly used.

Care of the outside of the IDA-2
Clean using a damp cloth with a mild household detergent. The polycarbonate case can be damaged if an abrasive cleaner is used, or by some solvents (e.g. methylated spirit).

Cleaning the inside of the IDA-2
Over a long period of use there may some 'scaling' of the inside tubes etc. Also there may be organic growth inside the measuring system. We suggest an occasional cleaning (e.g. every 3 months) as follows:

1. Mix a quantity of domestic kettle or coffee-maker descaler with water and inject approximately 20ml into the Model IDA-2.

2. Leave for 5 minutes, repeat once, then flush through with water (e.g. 100ml).

3. Inject 20ml of warm detergent solution and leave for at least 5 minutes. Then flush out with water.

4. Inject 20ml of chlorhexidine solution (or other disinfectant -hypochlorite is not advised). Leave for 10 minutes and flush out with water.

User Calibration and Performance Check
The IDA-2 has calibration set at the factory, and this should not change unless the unit becomes faulty. Users may wish to check for faults after a period of use or after shock to the unit. We suggest the pressure calibration is checked by connecting an external pressure gauge and syringe to the <u>Fluid-in</u> connector, initiating an occlusion test (<u>Fluid-in</u> must be vented to atmosphere at the start of the test), and then raising the pressure to a mid-range figure (e.g. 1Bar) and checking that pressure reading is approximately as expected.